

## **REMARKS**

### **1. Claim Status and Support**

Claims 13, 16, 57, and 61, as amended, and claims 9, 14, 46, 47, 59-60 are pending in the instant application. The amendments to the claims are fully supported by the specification and the claims as originally filed. No new matter has been added as a result of the claim amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### **2. Response to Declaration under 37 C.F.R. § 1.131**

The Patent Office asserts that the Declaration Pursuant to 37 C.F.R. § 1.131 filed March 29, 2007 “is ineffective to overcome the rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. 102(e) and claims 14, 57, and 59-61 under 35 U.S.C. 103(a) as being unpatentable by, or unpatentable over U.S. Patent Application Publication No. 2002/0068319 A1.” The Patent Office further asserts that “the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of U.S. Patent Application Publication No. 2002/0068319 A1 to either a constructive reduction to practice or an actual reduction to practice.” Finally, the Patent Office asserts that “the declaration fails to state that it was recognized, prior to September 24, 1999, that this open reading frame of the depicted evidentiary sequence encodes a polypeptide having the amino acid sequence set forth in the instant application as SEQ ID NO: 5.”

In response to these assertions, the Applicants submit herewith a Supplemental Declaration Pursuant to 37 C.F.R. § 1.131.

### **3. Rejection of claims 13, 16, 46 and 47 under 35 U.S.C. § 112, second paragraph**

The Patent Office has rejected claims 13, 16, 46, and 47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicant regards as the invention. The Patent Office asserts that claims 13, 16, 46, and 47 are indefinite “because claims 13 and 16 recite, ‘the nucleic acid molecule’” and “there is no antecedent basis for this limitation in the claims.”

Claims 13 and 16 have been amended as suggested by the Examiner to obviate the rejection. Applicants therefore, respectfully request that this rejection be withdrawn.

**4. Rejection of claims 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 112, first paragraph**

The Patent Office has rejected claims 13, 14, 16, 46, 47, 57 and 59-61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

A. Claims 13 and 57

With respect to claims 13 and 57, the Patent Office notes that “insofar as the claims are drawn to a polypeptide comprising SEQ ID NO: 5 (e.g., claims 9, 13, and 57), because the amino acid sequence disclosed is presumed intact, it is believed the written description has been met” (emphasis added). Claims 13 and 57 have been amended as suggested by the Examiner to obviate the rejection. Applicants therefore respectfully request that this rejection be withdrawn.

B. Claim 14

Applicants are unclear as to whether claim 14 has been rejected given the following statement in the Action: “Claim 14 encompasses polypeptides comprising the amino acid sequence of SEQ ID NO: 6, though otherwise having varying structures; nonetheless, there is a reasonable presumption that the claimed polypeptides will have or retain the function [of] a polypeptide consisting of the amino acid sequence of SEQ ID NO: 6. It is for this reason that claim 14 has not been included in this rejection” (emphasis added). Thus it is unclear as to whether the Patent Office intended to include claim 14 in this rejection.

As written, claim 14 recites “an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 6, optionally further comprising an amino-terminal

methionine” (emphasis added). As noted above the Action states that “insofar as the claims are drawn to a polypeptide comprising SEQ ID NO: 5 (e.g., claims 9, 13, and 57), because the amino acid sequence disclosed is presumed intact, it is believed the written description has been met” (emphasis added). Paragraph 79 of the specification states that

a mature Secs-1 polypeptide may also include other modifications such as proteolytic processing of the amino terminus (with or without a leader sequence) and/or the carboxy terminus, cleavage of a smaller polypeptide from a larger precursor, N-linked and/or O-linked glycosylation, and the like. An exemplary mature Secs-1 polypeptide is depicted by the amino acid sequence of SEQ ID NO: 3 or SEQ ID NO: 6.

Thus, the specification clearly states that the amino acid sequence of SEQ ID NO: 6 is a mature form of the Secs-1 polypeptide and that modifications can be made to the mature form “with or without the leader sequence” which includes “amino terminus” modifications. One of ordinary skill in the art would easily determine the mature form of the polypeptide of SEQ ID NO: 5 with or without the leader sequence. Furthermore, the specification provides this information and the specific sequence identifier as noted above. Moreover, Figure 2 of the specification illustrates both the nucleic acid sequence of SEQ ID NO: 4, and the amino acid sequence of SEQ ID NO: 5 with the signal peptide indicated by underlining. As noted in the Brief Description of the Figures on pages 7-8, the “predicted signal peptide is indicated (underlined).” Thus, Figure 2 illustrates the sequence of both the leader peptide and the mature form which corresponds to SEQ ID NO: 6. Finally, as noted by the Patent Office, “there is a reasonable presumption that the claimed polypeptides will have or retain the function [of] a polypeptide consisting of the amino acid sequence of SEQ ID NO: 6.” Thus, the specification and the original claims clearly recite, “an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 6, optionally further comprising an amino-terminal methionine” (emphasis added) with the requisite clarity and particularity necessary to permit the skilled artisan to immediately envision the members of this genus of mature Secs-1 polypeptides. Applicants therefore respectfully request that this rejection be withdrawn.

### C. Claim 16

With respect to claim 16, the Patent Office asserts that claim 16 is “broadly

directed, in the alternative, to any polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence as set forth in SEQ ID NO: 4,...or a nucleic acid sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5-not necessarily a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.” Claim 16 has been amended as suggested by the Examiner to obviate the rejection. Applicants therefore respectfully request that this rejection be withdrawn.

D. Claim 61

With respect to claim 61, the Patent Office asserts that “the claimed polypeptide need not consist of an amino acid sequence of SEQ ID NO: 5; and moreover, the claimed polypeptide does not necessarily comprise SEQ ID NO: 5.” Claim 61 has amended as suggested by the Examiner to obviate the rejection. Applicants therefore respectfully request that this rejection be withdrawn.

**5. Rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 102(e)**

The Patent Office has maintained the rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0068319 A1. As noted above, the Patent Office has deemed the evidence submitted to be “insufficient to establish diligence from a date prior to the date of reduction to practice of U.S. Patent Application Publication No. 2002/0068319 A1 to either a constructive reduction to practice or an actual reduction to practice.” The Action goes on to note that the amended claim set, drafted by the Examiner,

would be considered to distinguish patentably over the art of record in this application with the provision that Applicant furnish a supplemental declaration under 37 C.F.R. § 1.131 stating that it was recognized, prior to September 24, 1999, that the open reading frame of the depicted evidentiary sequence, initiating with the first codon encoding methionine (i.e., the sequence ATG at positions 29-31 of that sequence) encodes a polypeptide having the amino acid sequence set forth in the instant application as SEQ ID NO:5.

Applicants respectfully disagree with the Action’s assertion that a Supplemental Declaration is necessary to overcome the rejection. However, in an effort to expedite

allowance of the pending claims, Applicants herewith submit a Supplemental Declaration Pursuant to 37 C.F.R. § 1.131. Applicants contend that the attached Supplemental Declaration Pursuant to 37 C.F.R. § 1.131, as required by the Action, is sufficient to overcome the rejection of claims 9, 13, 16, 46, 47, 57, and 59-61 as well as claim 14 under 35 U.S.C. § 102(e) as being anticipated by Ni *et al.* Applicants contend that the Supplemental Declaration sufficiently asserts a reduction to practice of the claimed invention before September 24, 1999. Specifically, paragraphs 4-6 of the Declaration state that:

At a date prior to September 24, 1999, we recognized that the open reading frame of the nucleotide sequence set forth in SEQ ID NO: 4, initiating with the first codon encoding methionine (i.e., the sequence ATG at positions 29-31 of that sequence), encodes a polypeptide having the amino acid sequence set forth in the instant application as SEQ ID NO: 5.

At a date prior to September 24, 1999, we determined that the putative signal peptide of Secs-1 consisted of residues 1-24 of the amino acid sequence set forth in SEQ ID NO: 5, thus establishing the mature form of the polypeptide set forth in SEQ ID NO: 6.

After isolating the secreted protein, we would have easily identified the amino-terminal residue of the mature form of the polypeptide set forth in SEQ ID NO: 6.

The Patent Office has provided a recommended set of claim amendments which includes the cancellation of claim 14. Claim 14 recites “an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 6, optionally further comprising an amino-terminal methionine.” As noted above, paragraph 79 of the specification discloses that

a mature Secs-1 polypeptide may also include other modifications such as proteolytic processing of the amino terminus (with or without a leader sequence) and/or the carboxy terminus, cleavage of a smaller polypeptide from a larger precursor, N-linked and/or O-linked glycosylation, and the like. An exemplary mature Secs-1 polypeptide is depicted by the amino acid sequence of SEQ ID NO: 3 or SEQ ID NO: 6.

Thus it is clear from the specification that the amino acid sequence of SEQ ID NO: 6 is the mature form of the Secs-1 polypeptide. Applicants understand that limitations cannot

be read into the claim from the specification, however this is not a limitation and the claim plainly recites “an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 6.” Furthermore, Figure 2 of the specification illustrates both the nucleic acid sequence of SEQ ID NO: 4, and the amino acid sequence of SEQ ID NO: 5 with the signal peptide indicated by underlining. As noted in the Brief Description of the Figures on pages 7-8, the “predicted signal peptide is indicated (underlined).” Thus, Figure 2 illustrates the sequence of both the leader peptide and the mature form which corresponds to the amino acid sequence of SEQ ID NO: 6. Finally, the Supplemental Declaration submitted herewith asserts a reduction to practice of the invention of claim 14 prior to September 24, 1999. Thus, Applicants do not believe that the cancellation of claim 14 is necessary. Taken together with the Supplemental Declaration, Applicants have shown that they reduced the claimed invention to practice before September 24, 1999. Applicants, therefore, contend that Ni *et al.* does not anticipate claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. § 102(e), and therefore, respectfully request that this rejection be withdrawn.

### CONCLUSION

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Rawlings believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,  
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